COVINGTON

Impact of Brexit on EU Medical Devices Regulation and Structures

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Food and Drug

The UK recently voted to leave the European Union in an advisory referendum. The impact of Brexit on medical devices regulation in the medium-to-long term will very much depend on the form a post-Brexit UK will take, the relationship that the UK chooses to have with the EU, and indeed the relationship that the EU is willing to accept. That will not become clear for some time as it will likely take at least two years for the UK to negotiate an exit from the EU from the point when the UK notifies the EU of its intention to leave, which will not be until October 2016 at the earliest.

In the short-term, however, from a legal perspective it is likely to be business as usual for the medical devices industry since EU law will continue to apply in the UK. Nevertheless, medical devices companies need to start considering what steps they should take to minimise impact and disruption if and when Brexit happens.

Potential "Models" Post-Brexit

There is a fundamental tension between the UK's stated desire to participate in the EU's internal market and its conflicting desires to enhance its sovereignty and to limit immigration, which were key drivers behind the vote to leave. In return for any participation in the EU internal market, the EU is likely to insist on free movement of persons. In other words, the UK will not benefit from free movement of goods and services to and from the EU without accepting immigration from the EU. The price of a free trade agreement with the EU may well also include acceptance of some EU social and employment regulation. This may ultimately force the UK out of the internal market.

There are many different possible outcomes of Brexit. For these purposes, however, we will limit ourselves to three relationships that could emerge and that help illustrate the potential impact of Brexit on device regulations and infrastructures:

- **The "EEA Model"**. The UK would need to apply to sign the European Economic Area (EEA) Agreement, joining Norway, Iceland and Liechtenstein as EEA member states that are not in the EU. The EEA Agreement would allow the UK to participate in the EU's internal market, but it would require the UK to implement into its national laws the bulk of EU legislation designed to facilitate free movement of goods, services, capital and persons. This includes all EU medical devices legislation and, as discussed below, the effects for companies under this model would be modest. However, EEA member states must accept free movement of EU citizens and that is likely to be difficult to accept for many in the UK.
- **The "EFTA Model"**. The UK could join Switzerland in the European Free Trade Association (EFTA). It would then enter into free trade relations with the EEA and EU by negotiating bilateral agreements on a case-by-case basis. It would not be obliged to implement EU laws, although the EU has in the past voiced concerns over Swiss "cherry-picking" of EU policies. There would be some pressure to allow for some free movement of workers, but the UK would have greater ability to control its own borders.

- **The "WTO Model"**. The final option would mean that the UK is independent of any existing free trade arrangements with the EU. In addition to seeking a new multilateral trade relationship with the World Trade Organization (WTO), the UK would need to seek a tailor-made bilateral free trade agreement with the EU, the EEA and other trading partners. Since the 1960s, the EU has negotiated bilateral free trade agreements with neighbouring countries and beyond. The first example is the EU-Turkey agreement, which has resulted in a customs union for industrial goods, but not services, since 2000. The more recent free trade agreements include the EU-Canada Comprehensive Economic and Trade Agreement (CETA), which accepts some degree of regulatory convergence. The other option would be to trade with the EU on the same basis as other countries, such as China, including accepting applicable import duties.

The Impact of Brexit

Each of the above options will differ significantly in terms of their impact on the existing medical devices regulatory scheme. Before discussing each of these options in turn, it is worth making some general comments.

Whatever the outcome of Brexit, the UK would lose much, if not all, of the influence it has in the EU legislative, policy and regulatory procedures since it would be relegated to an "observer" role. Rather than being able to influence and participate actively in the development of EU medical devices law and policy, it would simply need to implement legislation that the EU Commission, EU Parliament and EU Council adopt.

Despite this, the impact of any form of Brexit on medical device regulation would be less than on pharmaceutical regulations and structures. This is because the EU's current medical device rules do not require government pre-market review of medical devices, nor is there systematic regulation of the medical device supply chain. Rather, the integrity of medical device supply chains is a matter for the manufacturer and the device quality system that it defines.

National device regulators, such as the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), focus primarily on post-market monitoring of the safety of devices marketed in their jurisdictions and share relevant information with other member states. Although there may be less automatic sharing of information post-Brexit, this fundamental position will remain unchanged whether or not the UK remains in the EU.

Member states also do not participate in complex multi-jurisdictional, coordinated review and approval of devices, such as the centralized or decentralized/mutual recognition procedures for medicines. This means that the ability of member states to participate actively in, or influence, these procedures is less of an issue.

One area in which little will change is the pricing and reimbursement of medical devices in the UK. The EU does not have competency to regulate the manner in which Member States structure their health services and determine the products that are available under them. EU law requires only that reimbursement decisions are based on objective and justifiable criteria and that pricing and reimbursement decisions are made efficiently and on a non-discriminatory basis. We expect that the NHS and the UK's healthcare systems will remain largely unchanged.

The Options

The impact of Brexit will depend largely on the extent to which the UK disengages and whether it remains part of the EEA, joins the EFTA or disengages even further.

The "EEA Model"

The UK would need to apply to sign the European Economic Area (EEA) Agreement, joining Norway, Iceland, and Liechtenstein as EEA member states that are not in the EU.

The EEA Agreement would allow the UK to participate in the EU's internal market, but it would require the UK to implement into its national laws the bulk of EU legislation designed to facilitate free movement of goods, services, capital, and persons. This includes EU medical devices legislation. The three key pieces of EU medical devices legislation (namely, the Active Implantable Medical Devices Directive 90/385/EEC, the Medical Devices Directive 93/42/EEC and the *In Vitro* Diagnostic Medical Devices Directive 98/79/EC) are already subject to the EEA Agreement. The UK would also implement the EU medical devices and *in vitro* medical devices (IVD) regulations once they are adopted and replace the directives. These new regulations will not bring a fundamental change to the Brexit analysis. However, there may be technical aspects for companies to consider given the much more detailed nature of the new rules.

This would mean that CE-marks would remain valid and devices that conform to the essential requirements could continue to be commercially distributed throughout the EEA, including the UK. UK entities could also continue to act as authorized representatives for manufacturers outside the EEA and hold technical documentation underlying the CE-mark in the UK. The new "person responsible for regulatory compliance" that will be required by the new EU medical devices and *in vitro* medical devices (IVD) regulations could be based in the UK.

The "EFTA Model"

If the UK decided to follow the Swiss route and opt for EFTA membership outside of the EEA, the EU medical devices rules will no longer apply, unless the UK enters into a bilateral treaty to that effect with the EU.

For example, Switzerland has implemented the EU medical devices directives into its national laws and has entered into treaties with the EU and the EFTA member states (including Norway, Iceland and Liechtenstein) under which it recognizes the conformity assessment procedures for medical devices marketed in the EU and *vice versa*. This allows Swiss or EU authorities, as applicable, to mutually accept reports and certificates issued by the recognised conformity assessment bodies in the other territory, as well as manufacturer's declarations of conformity certifying conformity of products to the applicable medical devices legislation. Switzerland therefore allows devices lawfully sold in the EU to also be sold in Switzerland, and the EU allows devices lawfully sold in Switzerland to also be sold in the EU.

The UK could potentially seek to follow the Swiss model and enter into a mutual recognition agreement with the EU. This would allow the EU or UK authorities, as applicable, to mutually accept devices lawfully marketed in the other territory. It would also mean that the EU could continue to recognise conformity assessments conducted by UK notified bodies, such as the British Standards Institution (BSI). Further, the UK manufacturer could continue to act as the legal manufacturer for the purposes of the medical device regulations and would not need to designate an authorized representative within the EEA. There would also be no requirement for a UK company to comply with pre-launch notification requirements in the EEA. The EEA would reciprocally recognise any registrations filed in the UK.

An agreement between the EU and the UK would not, however, provide the UK with any rights for mutual recognition of medical devices in Switzerland. The UK would need to enter into a separate agreement with Switzerland for this purpose.

The "WTO Model"

The last option would presume a total separation of the UK systems for medical devices regulation from the EU. Medical devices for use in the UK would be assessed in accordance with laws and standards that the UK would adopt, overseen by the MHRA. There may be scope, similar to the position between the EU and Turkey, for mutual recognition of conformity assessments conducted by notified bodies. However, this would depend on the terms of the resulting agreement.

Manufacturers in the UK wishing to distribute their products in the EEA would need to comply with EU device rules and appoint an authorized representative in the EEA, and the underlying technical file supporting the CE-mark would need to be held in the EEA by the authorized representative. However, the EU model with its inherent flexibility is an approach that many non-EEA jurisdictions are adopting and we consider it likely that the UK would also do so, particularly given the increasing global harmonization in the sector.

Summary

The full effects of Brexit will remain unclear until the UK's new relationship, whatever that may be, is established with the EU. In the meantime, companies will undoubtedly wish to begin planning for Brexit. At a minimum, companies should conduct a regulatory mapping exercise to check the following:

- Do UK entities act as the legal manufacturer of the company's medical devices and, consequentially, hold the CE-mark for the products?
- Do UK entities act as the authorized representatives of non-EEA manufacturers of medical devices?
- Do UK entities hold the technical documentation supporting the CE-marking of the company's medical devices?
- Have UK entities made pre-launch registrations of devices, either as manufacturers or authorised representatives of non-EEA manufacturers?
- Have UK-based notified bodies been involved in the CE-marking process of the company's medical devices?
- To what extent are UK companies important elements of a company's medical device supply chain?

Companies may also wish to start establishing greater links with, or a presence in, non-UK countries within the EU to ensure they can continue to influence EU laws and procedures.

Covington will be hosting a webinar: **Brexit: Impact on Medical Device Regulation and Structures** on Wednesday, July 13 at 5 p.m. BST/6 p.m. CEST. Please click here to register.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs and Devices practice:

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